K031186
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MAY - 6 2003

BARD ENDOSCOPIC TECHNOLOGIES
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter's Name:	C.R. Bard, Inc., Bard Endoscopic Technologies Division
Submitter's Address:	129 Concord Road, Billerica MA 01821-7031
Contact Person:	Thomas Hirte
Contact Person's Telephone Number:	(978) 262-4867
Contact Person's FAX Number:	(978) 262-4878

B. Device Name:

LUMINEXX™ Endoscopic Biliary Stent

C. Predicate Devices:

Bard® memotherm® Endoscopic Biliary Stent

D. Device Description:

The LUMINEXX™ Endoscopic Biliary Stent is a stenting system designed to maintain the patency of biliary ducts obstructed by malignant biliary strictures. The device includes the self-expanding LUMINEXX™ Biliary stent pre-loaded on a delivery system. The 7.5F delivery system is compatible with a 3.2 mm endoscope working channel and accepts a 0.35" guidewire. The stent is available in 8 and 10 mm diameters, and 40, 60, 80, and 100 mm lengths. The working length of the delivery system is 190 cm.

BARD ENDOSCOPIC TECHNOLOGIES
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7161
Billerica, MA 01821-7031
978-663-8999

BARD

E. Intended Use:

The LUMINEXX™ Endoscopic Biliary Stent is indicated for use in the palliative treatment of patients with malignant biliary strictures.

F. Technological Characteristics Summary:

The LUMINEXX™ Endoscopic Biliary Stent is a metal mesh stent constructed of nitinol. Tantalum spoons on each end of the stent provide enhanced radiopacity. The stent is self-expanding and is packaged pre-mounted on a disposable delivery system.

G. Performance Data:

Design verification data demonstrated that the LUMINEXX™ Endoscopic Biliary Stent meets the same performance requirements and is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2003

Thomas Hirte, P.E.
Senior Regulatory Affairs Specialist
Bard Endoscopic Technologies
C. R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, Massachusetts 01821-7031

Re: K031186
Trade/Device Name: LUMINEXX™ Endoscopic Biliary Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: April 14, 2003
Received: April 15, 2003

Dear Mr. Hirte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031186

Device Name: Bard LUMINEXX™ Endoscopic Biliary Stent

FDA's Statement of the Indications For Use for device:

The LUMINEXX™ Endoscopic Biliary Stent is indicated for use in the palliative treatment of patients with malignant biliary strictures.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031186